

AMENDMENTS TO THE CLAIMS

1. (Currently Amended) A method of manufacturing a drug granule, comprising a granulation step of spraying only a solution of a water soluble drug on a crystal of said water soluble drug substantially without using a binder or in the absence of binder in a rotary fluidized bed granulate coating apparatus, wherein the drug granule has a granular strength of 650-2500 gf/mm<sup>2</sup>.

2. (Cancelled)

3. (Currently Amended) A drug granule obtained by a method comprising a granulation step of spraying only a solution of a water soluble drug on a crystal of said water soluble drug substantially without using a binder or in the absence of binder in a rotary fluidized bed granulate coating apparatus, wherein the drug granule has a granular strength of 650-2500 gf/mm<sup>2</sup>.

4. (Cancelled)

5. (Previously Presented) The drug granule of claim 3, having a particle size of 0.05 mm - 1.5 mm.

6. (Previously Presented) A pharmaceutical preparation comprising the drug granule of claim 3, and a pharmaceutical acceptable additive.

7. (Currently Amended) A coated granule obtained by a method comprising a step of spraying only a solution of a water soluble drug on a crystal of said water soluble drug substantially without using a binder or in the absence of binder in a rotary fluidized bed granulate coating apparatus to form a drug granule, wherein the drug granule has a granular strength of 650-2500 gf/mm<sup>2</sup>, and a step of coating said drug granule with a release control film coating agent.

8. (Cancelled)

9. (Previously Presented) The coated granule of claim 7, wherein the release control film coating agent is a sustained release agent or an enteric coating agent.

10. (Currently Amended) A method of manufacturing a coated granule, which comprises:

- (a) a step of spraying a solution of a water soluble drug on a crystal of said water soluble drug obtained by a method

comprising a granulation step of spraying only a solution of a water soluble drug on a crystal of said water soluble drug substantially without using a binder or in the absence of binder in a rotary fluidized bed granulate coating apparatus to form a drug granule, wherein the drug granule has a granular strength of 650-2500 gf/mm<sup>2</sup>; and

- (b) a step of coating said drug granule with a release control film coating agent.

11. (Cancelled)

12. (Original) A granule of a water soluble drug, which is substantially free of a binder and which has a granular strength of 650-2500 gf/mm<sup>2</sup>, having a crystal of said water soluble drug in a nucleus.

13. (Original) A coated granule comprising a granule of a water soluble drug, which granule comprises a crystal of said water soluble drug as a nucleus, being substantially free of a binder and having a granular strength of 650-2500 gf/mm<sup>2</sup>, and a release control film coating agent coated thereon.

14. (Original) A coated granule comprising an inner layer comprising the drug granule of claim 12 and an outer layer comprising a release control film coating agent.